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Advanced technology for personal biomedical signal logging and monitoring  
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### Abstract:

A basic technology (methods, hardware and software tools), purposely orientated to telemedicine, has developed. The approach foresees, from the control unit point of view, a new management philosophy central stations effectively distributed on network. All the patient devices are wearable. They are base intelligent and powerful controller, provided with large storage memory and with a reliable telephone telemetry and telemedicine applications using, if necessary, a digital approach. The necessary flexibility telemonitoring systems is obtained exploiting a modular approach in the design of both the personal and central control unit. Simply combining specific standardized components (analog front-end, processor communication interface), a complete family of instruments can be obtained ranging from a simple EKG capable to "play" the signal through the telephone to a multifunctional digital data logger, radio and/or telephone line. The control unit modular approach has led to a "web server" based design. The physician's own telemedicine service simply using his/her PC coupled by a modem to the telephone line, a standard Net-Browser. A new network service, the "Medical Provider", supplies the link (hardware and with the remote patients, assuring also the necessary data safety and security).

### Index Terms:

telemedicine; patient monitoring; Internet; biomedical telemetry; data loggers; computerised monitoring; electrocardiography; personal biomedical signal logging; advanced technology; software tools; hardware telemedicine; patient wearable devices; intelligent controller; large storage memory; reliable telephone telemetry; telemonitoring systems; modular approach; central control unit; simple EKG detector; multi digital data logger; web server based design; Net-Browser; Medical Provider service; remote patients; Internet; Intranet

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## ADVANCED TECHNOLOGY FOR PERSONAL BIOMEDICAL SIGNAL LOGGING AND MONITORING

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### Abstract

A basic technology (methods, hardware and software tools), purposely orientated to telemedicine, has been developed. The approach foresees, from the control unit point of view, a new management philosophy, leading to central stations effectively distributed on network. All the patient devices are wearable. They are based on an intelligent and powerful controller, provided with large storage memory and with a reliable telephone interface for telemetry and telemedicine applications using, if necessary, a digital approach. The necessary flexibility of telemonitoring systems is obtained exploiting a modular approach in the design of both the personal device and the central control unit. Simply combining specific standardized components (analog front-end, processor unit, communication interface), a complete family of instruments can be obtained ranging from a simple EKG detector, capable to "play" the signal through the telephone to a multi-functional digital data logger, radio and/or IR coupled to telephone line (cellular type included). The control unit modular approach has led to a "web server" based design. The physician can set up his/her own telemedicine service simply using his/her PC coupled by a modem to the telephone line, provided with standard Net-Browser. A new network service, the "Medical Provider", supplies the link (hardware and software) with the remote patients, assuring also the necessary data safety and security.

**Keywords:** Telemonitor, Telemedicine, Internet, Intranet

### Introduction

Telemedicine is the delivery of care to patients anywhere in the world by combining communications technologies (mainly the public telephone network) with medical expertise [1]. This is an emerging field that could have a revolutionary impact on health management, bringing the man and its needs in the core of technological progress. The main goal of telemedicine approach, namely to improve access to high quality medical care at affordable cost, can be pursued by means of a true distributed telemonitoring system. In this direction is addressed our work, having as a final aim the

fulfilment of a continuous, dynamic, interactive connection between the patient at home, and control stations, placed everywhere, ranging from hospital to family doctor. The advantage of this approach appears clear, harmonising, in the Health System, services quality and costs, two classically antithetical elements. The problem of telemedicine (in several branches of instrumental diagnostics: cardiology, pneumology, sport, etc.) is at present afforded by considerable fundings by public and private organisations. In this field, together with unattended, sophisticated, patient instrumentation, telecommunication means, if exploited in very effective medical organisation for the ambulatory telecontrol, are of crucial importance. Otherwise without an efficient telecontrol organisation, the remote monitoring remains a technological set of expensive gadgets. It seems to be fundamental, at the level of remote control station design, that the system is easily exportable to various telemonitoring realities. This approach constitutes an innovative philosophy in developing the central control station. In fact, we are approaching the problem by a client-server technique: a specialised centre, providing the maintenance and the safety of data, sets up a special "server", that is capable to connect peripheral devices and to provide a "client" interface on an Intra-net. In this way any PC platform and a standard network browsing program (i.e. Netscape) are worthwhile to constitute a control station, simply connecting the "server" through the net (i.e. Internet). This solution allows a true "environmental exportability" of the central control functions anywhere the medical knowledge is available, without any special purpose equipment.

For what concerns the majority of portable devices [2] exploiting the switched telephone line for communication, two different link are normally used: an acoustic coupling, for the more simple and less powerful systems, and a digital galvanic one for the more sophisticated systems. In the case of acoustic coupling, the FM modulation of an in-band carrier is normally used, while the digital transmission is accomplished by a modem. Today, cumbersome problems are faced in the acoustic transmission through digital telephone (namely GSM cellular technology), related to the unrecoverable errors induced by the statistical filter

that normally performs the voice data compression; in this sense the Authors are investigating on a proper pre-filter, to adapt the already developed analog transmitting system to the digital telephones. Anyway, as a matter of fact, the actual trend to digital approach in telephone communication probably will lead to a digital approach also in telemedicine.

### The instruments.

In some pathologies, related to cardiac rhythm alterations and potentially very dangerous, symptoms may be often sporadic; the possible very rare incidence of symptomatic episodes, few events in the week or in the month, renders not properly suitable the Holter investigation technique. In fact, this dynamic monitoring is normally used for 24 hours of EKG continuous monitoring; then it results too expensive in terms of instrumentation employment, time expensive, for the necessary post-analysis, and not always effective for recording very sporadic phenomena, during days and days.

The proposed system constitutes the simplest sentinel instrument to transmit, on symptom, and remote analyse, an EKG lead. The device, named CARDIOSOUND (Fig.1), implements a real time transmission using a carrier in the acoustic band frequency, modulated by the EKG signal, suitable to be transmitted on the telephone public net to the existing central stations, already used for the "Cardiotelefono" and "Cardiobip" devices [3], delivered by the Italian Telecom. The peculiar characteristic of such device is the miniaturisation: it is constituted by a light medal of about 5 cm of diameter and of 0.7 cm of thickness, automatically activated if pressed on the breast, where two electrodes, embedded in the faces, collect the electrocardiogram.

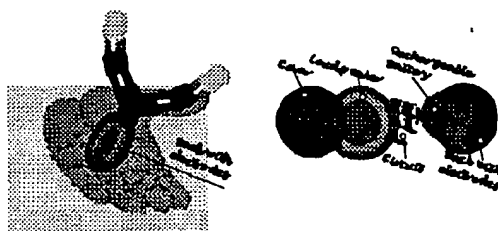


Fig. 1: The Cardiosound, capable of "playing EKG through the telephone line

The EKG FM modulated acoustic signal is on line transmitted, through a piezoelectric loudspeaker, to the handset microphone posed in the vicinity of the "medal". The embedded energy source (a lithium battery) can be refilled during the night, simply placing the device on a special purpose recharging set, main or battery powered.

CARDIOBIT, shown in fig. 2, constitutes a modern version of the already known "Cardiobip", developed by the Authors in the past 80's and delivered by the Italian Telecom. As an improvement, it uses an eight channels analog to digital converter, embedded in the control microprocessor; it is equipped with a 12 lead EKG front-end and is provided of analog (FM acoustic carrier) and digital (by modem) telephone transmission capability of on line or recorded EKG.

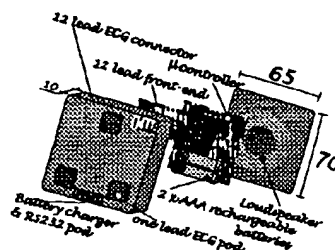


Fig. 2: The Cardibit; it allows to record and to transmit the complete 12 leads EKG through the telephone by digital or analog communication technique.

The system allows the following ways of operation:

- Automatic acquisition of one or 12 EKG contemporaneous leads from the electrode pod, in the first case, or from a patient cable, connected to disposable electrodes or to a special wearable electrode "corset", in the second one.
- Possibility to record EKG passages and real time or off line transmission by telephone.
- Manual activation of the acquisition/transmission.
- Analog transmission by acoustic coupling to the telephone handset, (modulated frequency- FM- of an acoustic carrier).
- Digital transmission of the recorded signals by a modem, integrated in the charging battery set.

About three hours of recording in benches of varying length (provided by automatic identifiers). The system is contemporaneously compatible with "analog" standard receiving central station (however adaptable to any system that uses transmission acoustic FM carriers). Using the modem option, integrated in the charging battery set, the system allows telephone digital transmission of the recorded passages toward any computerised station.

CARDIOLOG represents an evolution of the instrumentation for dynamic recording of Electrocardiogram (Fig. 3): it implements a true Tele-Holter device and is capable to provide local processing and the communication of results and signals to a central unit by a completely digital technique. In practice, it consists in a "data logger" with interchangeable front-end and with a minimum set of 8 analog channels in input.

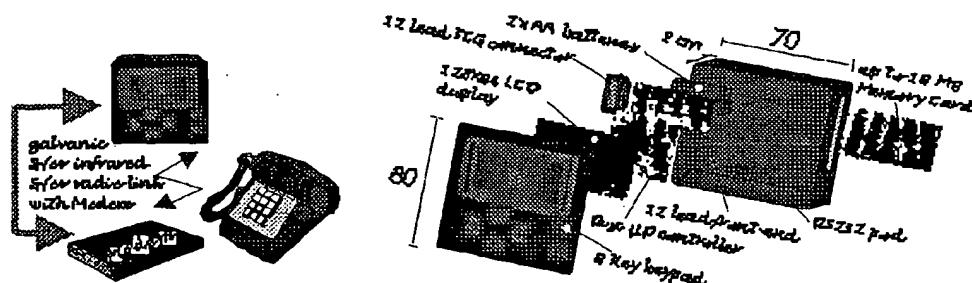


Fig. 3 The Cardilog device and a schematic representation of its possible links to the telephone line.

The system is equipped with RS232 standard interface for bi-directional digital communications. The on board firmware foresees an owner "BIOS" and an operating system that allows the use driven by different management software, loaded in the RAM space from Memory Card and/or by remote control through the serial port. The graphic display and the 6 keys keyboard constitute the confidential interface towards the user, together with a piezoelectric loudspeaker producing tones. During the monitoring instrument installation in the analysis medical centre, the monitoring protocol is selected and tuned on the specific patient; the device is also programmable by telemetry and/or by telephone. Depending on the program, the dynamic continuous monitoring, and/or on events collection of the above mentioned biological variables, is allowed.

The link to the telephone net, supervised by a Kermit communication protocol, is controlled by a digital modem using a galvanic link; alternatively it is available a radio and/or infrared linkage to a purposely adapted modem, connected to the telephone line. Additional miniaturised Spread Spectrum Rx/Tx devices have been considered to use the systems with PCs in wire-less nets. Two AA 1.5 V alkaline batteries assures the function of the system for more than 24 hours; data back-up battery facility is provided. Analog communication by acoustic FM modulated carrier is also available.

BIOLOG, schematically represented in fig. 4, constitutes a general purpose system for multifunctional dynamic monitoring of biosignals. The basic version foresees the contemporaneous measurements of arterial blood pressure and blood oxygen saturation; an EKG lead is also provided to get the rhythm, while two accelerometer channels have been foreseen for application in movement rehabilitation [4].

At present CO<sub>2</sub> monitoring is also in development. The electronics is equipped by a specialised front-end that basically contains:

- an EKG channel (used also to synchronise the other measures);

- an optoelectronic system for detecting the peripheral plethysmographic wave (on the finger and/or on the ear lobe).

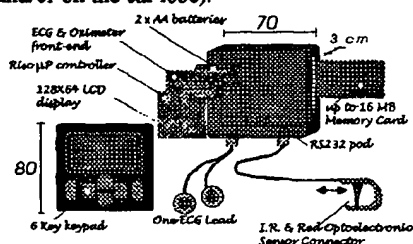


Fig. 4: The Biolog for a multifunctional telemonitoring service.

The blood pressure, beat by beat, is delivered by a mathematical original model that correlates the peripheral blood volume wave to selected phases of the cardiac cycle.

The oxygen arterial blood saturation is obtained by a digital algorithm, exploiting the blood pulse and the different absorbance of both the total hemoglobin and the oxi-hemoglobin, in the red and near infrared light band.

They are possible, according to the programmed protocol, the recording on memory card of the whole (or part if selected) biological detected variables, the local processing, the trend production and, finally, the digital data transmission to a central control station.

The link to the telephone is provided through modem, by galvanic connection to an RS232 port, or as an option, by radio and/or IR interface (IRDA). The use in telemetry nets is provided by special embedded communication software and hardware coupling the system to a commercial lightweight, inexpensive Radio-modem mod. RFM433-LC, produced by the Stamptronic Company, France. Also cellular telephone transmission has been foreseen, using an ad hoc developed software on the portable device in conjunction with a GSM cellular apparatus WM01-G900 by Wavecom company.

## Discussion

As demonstrated by the brief previous description, the present technology appears worthwhile to produce cheap portable devices for remote patient monitoring using the public telephone line. The effective diffusion of this methodology is mainly related to two main problems: the clinical use, that up to now has been principally focused to emergency, and the organisation engagement of the central control station. These two facts are also related together; in fact, when the system is devoted to an emergency use, continuous medical assistance availability is necessary and also the requests in term of the technical features of the implants result very severe. On the contrary, our approach is focused to the use of telemonitor mainly for the sub-acute phase of the illness, in post hospitalisation phase and in chronic disease. This field of intervention spreads the possible applications and permits the use of existing network (i.e. internet backbones) to support a guaranteed "quasi" on line assistance, moving the technical difficulties to an well established service, the Medical Provider, that assures all the network services, automatic delivering of special communication/processing software and, finally, the data management. Furthermore, this organisation allows the physician to off line and/or on line collect data from the remote patient, by his/her Intranet connection with the local Medical Provider.

The functions up to now implemented in setting-up the pilot Medical Server are resumed in the following:

1. managing of the telephone communication with analog (decoding and digital conversion of the signal transmitted as a FM modulated acoustic carrier) and digital (asynchronous up to 19200 baud) techniques;
2. automatic computerised ECG analysis, if requested;
3. data storing and retrieval means;
4. communication and application programs and service maintenance with special reference to the data safety and security and external/internal data access.

By means of some "free of charge" telephone numbers, the built up pilot architecture allows the communication with the provider; this facility avoids the problems to the calling patient, in case of necessity, possibly related to the ISP communication (busy line, temporary unavailability of the ISP-Internet connection, etc.).

The access to the medical information by the remote physician PC is managed by sophisticated Internet applications exploiting the Client/Server architecture DCOM (Distributed Component Object Model). As an example a print-out obtained on the physician PC connected to the provider web site to retrieve data coming from a remote controlled

patient, just collected and processed, is shown in fig. 5

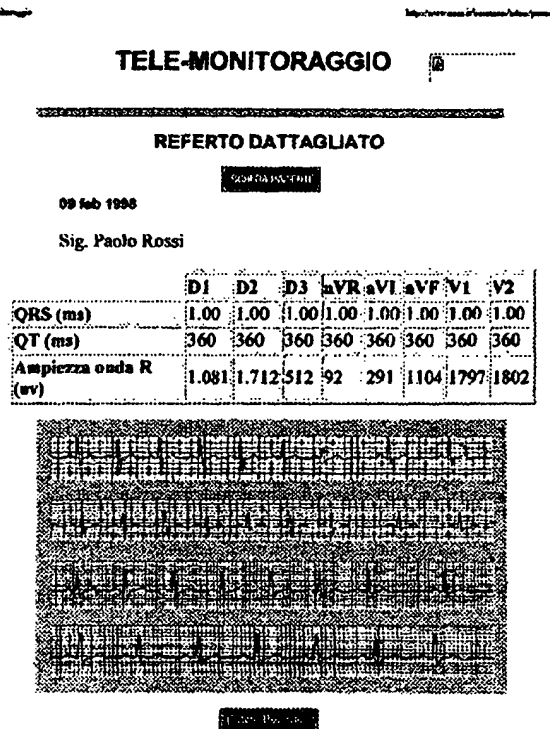


Fig. 5: Processed electrocardiographic data collected on a remote patient, as appear on the pilot user interface of the Intranet connected physician PC.

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